The Secca® Procedure for the Treatment of Fecal Incontinence: Definitive Therapy or Short-Term Solution*

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ABSTRACT

The treatment of fecal incontinence by means of radiofrequency energy is based on the concept that collagen deposition and subsequent scarring may increase one's ability to recognize and retain stool and permit improved continence. The procedure is undertaken on an outpatient basis. Individuals may be considered candidates even if they have a potentially reparable defect since the technique does not limit one to the application of a subsequent procedure. Clearly, those for whom other treatment methods have failed and those who have no other reasonable option in the management of their fecal incontinence should be considered for this procedure. Preliminary results are quite encouraging, and the results of a prospective, sham-controlled, randomized clinical trial are awaited.

KEYWORDS: Fecal incontinence, radiofrequency, Secca®

Objectives: Upon completion of this article, the reader should have an understanding of radiofrequency treatments for fecal incontinence.

Fecal incontinence represents not only a social and physical debility, but it can also become a psychological burden that profoundly impacts an individual's quality of life. Fecal incontinence may be defined as the unwanted release of mucus, gas, or stool. Several approaches to management are recommended, depending on the etiology of the condition. These include dietary modification, perineal exercises, medications, biofeedback, and a host of surgical alternatives. The ideal candidate for surgical treatment is the individual with a sphincter defect, but even with an anatomically successful direct sphincter repair, failure rates with respect to functional results are quite high.

Several less invasive approaches to the treatment of fecal incontinence have been developed in recent years. One of these is the application to the internal anal sphincter of radiofrequency (RF) energy. The hypothesis that this may be an effective alternative originated from its benefit in a variety of other conditions, such as gastroesophageal reflux disease (GERD), benign prostatic hypertrophy (BPH), and obstructive sleep apnea.[1–4] In theory, RF-induced injury to the internal anal sphincter should, ideally, cause collagen deposition and fibrosis with the potential for tightening of the affected area.

RF energy has been used for electrosurgical techniques (cutting and coagulation) since the 1920s. When

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Fecal Incontinence; Editor in Chief, David E. Beck, M.D.; Guest Editor, Sharon G. Gregorcyk, M.D. *Clinics in Colon and Rectal Surgery*, volume 18, number 1, 2005. Address for correspondence and reprint requests: Marvin L. Corman, M.D., Department of Surgery, Stony Brook University, HSC 18-060, Stony Brook, NY 11794-8191. E-mail: marvin.corman@stonybrook.edu. [1]Long Island Jewish Medical Center, New Hyde Park, New York; [2]Department of Surgery, Stony Brook University, Stony Brook, New York. 1531-0043,p;2005,18,01,042,045,ftx,en;ccrs00203x.

Figure 1 Secca handpiece. (A) Unit with handle/anoscope, light attachment, RF delivery connector, suction and irrigation. (B) Close-up with needles deployed. (Courtesy of Curon Medical, Fremont, CA.)

delivered to tissue in the frequency range of 200 kilohertz to 3.3 megahertz, RF energy results in vibration of water molecules and subsequent frictional heating. The Secca® System (Curon Medical, Inc., Fremont, CA) is designed to deliver temperature-controlled RF energy to the internal sphincter. The RF energy handpiece is a clear anoscopic barrel with four nickel-titanium curved needle electrodes (22 gauge, 6 mm in length; see Figure 1). The needle electrodes are deployed through the mucosa of the anal canal and into the internal sphincter muscle. Upon deployment, there is a reduction in electrical impedance, indicating proper electrode penetration below the mucosal surface. Temperature is monitored automatically and processed by a temperature-control mechanism, which adjusts RF output to achieve a target temperature of 85°C at the tip of the needle electrode (Fig. 2). Chilled water is perfused through the handpiece to cool the anoderm while the deeper tissue around the needle electrodes is heated. Anoderm temperature is continuously monitored, and energy delivery automatically ceases if anoderm temperatures exceed a preset limit of 42°.

TECHNIQUE

The procedure is undertaken on an outpatient basis, in an ambulatory surgical facility or endoscopy unit most frequently using no more than a local anesthetic field block and conscious sedation. The patient is placed in the prone-jackknife position, and the handpiece is inserted and positioned with the needles 0.5 cm distal to the dentate line. The needles are then deployed into the tissue and impedance is checked for proper tissue contact. Once appropriate tissue penetration is achieved, the operator initiates RF energy delivery, and the four-channel generator delivers this energy to all four electrodes to achieve a target temperature of 85°C. A one-minute treatment is applied to each set. Ideally, a total of 20 sets of four lesions each are created, beginning 5 mm distal to the dentate line and at 5-mm increments

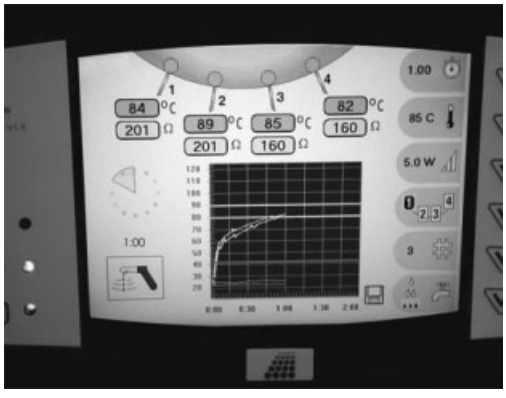

Figure 2 Monitor screen with schematically shown four electrodes with corresponding temperatures (84°C to 86°C) and impedances. Note that temperature range over time is in the therapeutic range. Also note flat two lines at the bottom of the graph showing cool surface temperatures. (Courtesy of Curon Medical, Fremont, CA.)

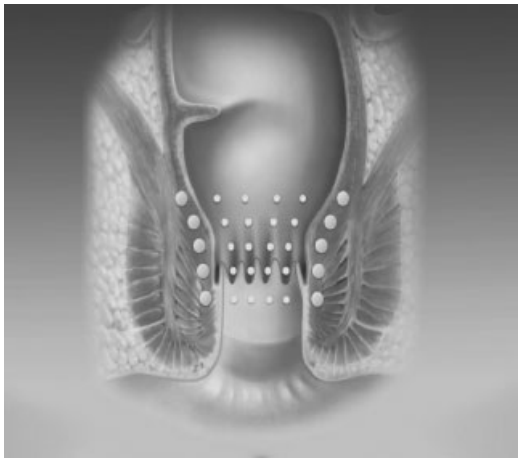

Figure 3 Schematic illustration of electrode deployment sites. Four quadrants are treated in a similar manner. (Courtesy of Curon Medical, Fremont, CA.)

proximal to the original treatment site (Fig. 3). Care must be taken during the anterior treatment in a woman to avoid penetrating the vagina. All four quadrants are treated in like manner, creating (if possible) 20 sets of lesions, each composed of four needle insertions. Depending on the number of sets, the procedure takes ~30 minutes. Patients are discharged in accordance with the criteria required for conscious sedation in an ambulatory setting or general anesthesia if so performed.

RESULTS

Takahashi and colleagues[5] performed the initial clinical trial in which the feasibility, safety, and efficacy of the concept of RF energy delivery to the anal canal for the treatment of fecal incontinence was investigated. Ten women, with incontinence of varying etiologies, were treated with this device. Median discomfort by a visual analog scale (0 to 10) was 3.8 during treatment and 0.9 2 hours following the procedure. Delayed bleeding (3 weeks post-treatment) was a complication in four cases, three of which were self-limited and one of which required suturing. All parameters of the fecal incontinence/quality of life index were improved—that is, lifestyle, coping, depression, and embarrassment. The only objective change was an improvement in both initial and maximal tolerable rectal distention volumes. A report of these individuals at 2 years revealed a highly significant improvement in the mean Cleveland Clinic Florida Fecal Incontinence Score (CCF-FI) from 13.8 to 7.3, as well as a statistically significant improvement in the quality of life score (FIQL).[6] The report also demonstrated no significant decline in results from 1 to 2 years. Of the seven women who required the use of a protective pad, four were able to abandon this method of security.

A five-center study, in which the senior author participated, involved 50 patients (43 women) with fecal incontinence, all of whom were failures of medical or surgical management.[7] Inclusion criteria included incontinence for stool as least once per week for 3 months. At baseline and at 6 months, the patients completed CCF-FI and the FIQL questionnaires as well as a social function questionnaire (SF-36). All subjects underwent anorectal manometry, pudendal nerve terminal motor latency, and anorectal ultrasound testing at baseline and 6 months. At 6 months, the mean CCF-FI score had improved from 14.5 to 11.1 ($p < 0.0001$). All parameters in the FIQL were improved ($p < 0.001$). There was an overall statistically significant improvement in the days with fecal incontinence, the days with gas incontinence, the incidence of pad soiling, the days with urgency, and the days with fear of fecal incontinence. With the exception of one center's data, no objective changes were noted in physiologic studies with the exception that resting anal sphincter length increased by 25% ($p = 0.019$). Complications included mucosal ulceration (one superficial, one with underlying muscle injury) and delayed bleeding (one).

COMMENT

There is certainly a gap between nonoperative treatment of fecal incontinence and that of surgery. The Secca® procedure is intended to offer a less-invasive option for the management of anal incontinence as compared with surgical alternatives. The Secca® System received clearance from the US Food and Drug Administration in early 2002 for the treatment of fecal incontinence. While it is no longer considered an investigational approach there is a unique study currently being undertaken—that of a prospective, randomized, *sham-controlled* United States trial, in which the Secca® procedure is compared with a placebo, anoscopic treatment. This is the only clinical trial of its kind that will meaningfully assess the outcome of any of the interventional options for the treatment of fecal incontinence.

Regarding the Secca® procedure and the currently available results, there is a favorable risk/benefit ratio when compared with alternative treatments. The Secca® procedure is a minimally invasive, ambulatory procedure, and patients may return to normal activities within 48 hours. With respect to individuals who are potential candidates, it could be considered as first-line therapy for those with fecal incontinence, since "no bridges are burned." That is not to say that someone with a reparable sphincter defect would be better served by RF treatment, simply that it is believed that this approach would not preclude a subsequent operation. It should also be considered following a procedure or a treatment that has had less than satisfactory results or in someone who cannot tolerate an operation. Finally, it may certainly be offered as a "last resort" to a patient for whom there is no alternative except fecal diversion.

While progress has been made in the areas of requisite training and case of use, a clearer treatment algorithm for the management of fecal incontinence is still required.

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